REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herewith, which place the application into condition for allowance or into better condition for appeal.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-95 are pending. No new matter is added.

It is submitted that these claims, as originally presented, were in full compliance with the requirements of 35 U.S.C. §112. Further, the remarks presented herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §101, §102, §103, or §112. Rather, the remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

A Petition for Extension of Time - 2 months - is enclosed. If any additional fee is deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

II. 35 U.S.C. § 103 REJECTION

Claims 1-80, 88 and 89 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,464,933 to Bolognesi et al., the Reddy article and U.S. Patent No. 5,795,569 to Bartley et al. The rejection is traversed.

Applicants' invention is directed to, *inter alia*, a compound of formula (I):

$$R_1\text{-}(CH_2CH_2O)_n\text{-}CH_2CH_2\text{-}O\text{-}(CH_2)_m\text{-}\overset{\overset{O}{\|}}{C}\text{-}NH\text{-}(CH_2)_p\text{-}CH_2\text{-}NHT20.$$

None of the cited documents teach, suggest or motivate a skilled artisan to practice the instantly claimed invention.

The Office Action is apparently proposing that anything pegylated must be obvious. Such a proposition is, respectfully, misguided.

Bolognesi relates to peptides having anti-retroviral activity. The patent, however, fails to teach or suggest the instantly claimed invention having a compound of the formula I.

Bartley relates to megakaryocyte growth and development factors and purportedly teaches an aldehyde as a coupling moiety. The Office Action extrapolates that one skilled in the art would somehow combine Bartley with the T20 protein of Bolognesi in order to practice the instant invention. But there is no teaching, suggestion or motivation *in either Bolognesi or Bartley* that would lead one skilled in the art to practice Applicants' invention. Against this background, such a rejection is impermissible. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (B.P.A.I. 1993). Indeed, absent such a disclosure, an obviousness rejection must fail as a matter of law. *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992).

Reddy is a review article that outlines the advantages *and disadvantages* of injectable drug delivery mechanisms. For example, Reddy acknowledges that not all pegylated proteins are alike and repeatedly warns that experimentation is required on a protein-by-protein basis. (*See, e.g.,* Abstract at 915). Further, Reddy points out that "a PEG chain that is insufficient to protect the molecule offers no advantage to the parent molecule, while the use of too large a PEG conjugate and too many PEG conjugates attached can result in decreased biologic activity." (Reddy at 919).

Applying the Reddy article in its *entirety*—as required by the Federal Circuit—a skilled artisan would realize that simply pegylating a protein does not automatically result in a compound having, for example, improved performance and pharmacokinetic characteristics. Thus, the expectation of success is lacking in the combination of Bolognesi, Reddy and Bartley, thereby rendering the obviousness rejection void *ab initio*. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Examiner's reliance on these three documents amounts to a classic "obvious to try" scenario. That it, a skilled artisan would arguably believe that it is obvious to try to pegylate T20. "Obvious to try," however, is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification."

Alternatively, Applicants' invention is a *selection* invention. Bolognesi alleges, in Tables 1 and 2 of columns 6 and 7, that the T20 peptide may be modified with a broad *genus* of moieties. These moieties include, for example, an amino group, a hydrophobic group, including but not limited to carbobenzoxyl, dansyl, or t-butyloxycarbonyl; an acetyl group; FMOC; a macromolecular carrier group including but not limited to lipid-fatty acid conjugates, polyethylene glycol, and carbohydrates. Applicants have discovered, for example, that the pegylated T20 polypeptide having the instantly claimed structure possesses improved performance and pharmacokinetic characteristics. Thus, Applicants' selection invention is patentable.

Consequently, reconsideration and withdrawal of the Section 103 rejection based on the preceding documents are respectfully requested.

CONCLUSION

In view of the remarks herewith, the application is in condition for allowance or in better condition for appeal. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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